REMARKS

Preliminary Remarks

A marked up copy of the amended claims is attached hereto as Exhibit A. In addition, a copy of currently pending claims 1, 4, 5, 7-12, 26, 29-30, 32-37, 40-41 and 43-51 as they would appear after entry of this amendment is attached hereto as Exhibit B. Independent claims 1, 26 and 37 have been amended to recite "a solid-free, oleaginous pharmaceutical or cosmetic carrier." Applicants submit no new matter has been added.

The Claimed Subject Matter

The invention is directed to a solid-free oleaginous or oil-based pharmaceutical or cosmetic carrier containing, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent, wherein said solidifying agent is selected from the group consisting of at least one long chain fatty alcohol having at least 15 carbon atoms in its carbon backbone and at least one fatty acid having at least 18 carbon atoms in its carbon backbone. The proportions and composition of the solidifying agent and hydrophobic solvent are selected such that under ambient conditions the carrier is semi-solid at rest and liquefies upon application of shear forces thereto.

The Outstanding Rejections

Claims 1, 4, 5, 7-12, 26, 29-30, 32-37, 40-41 and 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vatter, et al. (6,224,888). The examiner alleges that it would have been obvious at the time the invention was made to modify the composition of Vatter by selecting suitable oil emollients and amounts as disclosed because of the expectations of successfully producing a cosmetic carrier suitable for active ingredients.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vatter further in view of Geria (4,992,478). The examiner alleges that it would have been obvious at the time the

invention was made to have modified the composition of Vatter by adding the medicaments and the disorders as taught by Geria with the reasonable expectations of broadening the range of functions for the base composition.

Rejection over U.S. Patent No. 6,224,888 to Vatter

Applicants respectfully traverse the rejection of claims 1, 4, 5, 7-12, 26, 29-30, 32-37, 40-41 and 43-50. Applicants maintain their position that the Vatter patent does not suggest the instantly claimed cosmetic or pharmaceutical carrier because the compositions disclosed therein do not exhibit the instantly claimed carrier properties, namely, that the carrier is semi-solid at rest and liquefies upon application of shear force thereto.

The compositions disclosed in Vatter would not liquefy upon application of shear force because of the presence of oil-insoluble powders (solids) in each disclosed composition. Such solids include inorganic salts, *e.g.*, titanium oxide and zirconium aluminum; silica; and pigments. The products described by Vatter require a solid consistency and should not be flowable, in order to remain on the application site. The presence of such solids would prevent the product from being liquefied upon application of shear force.

With respect to the presence of such solids in each of the examples in Vatter, applicants would like to direct the examiner's attention to the following examples. The lipstick composition disclosed in Example I contains Red 21 Aluminum Lake (7.0 wt. %) and titanium dioxide (4.7 wt. %). The lipstick composition disclosed in Examples II and III contain silica L-700 (1.0 wt. %) and pigment (9.0 wt. %). The lipstick composition disclosed in Example IV contains pigment (9.0 wt. %). The antiperspirant gel stick disclosed in Example V contains aluminum zirconium (25.0 wt. %) and talc (3.0 wt. %). The solid antiperspirant stick disclosed in Example VI contains aluminum chlorohydroxide (40.0 wt. %). The solid antiperspirant stick disclosed in Example VII contains zirconium chlorohydroxide (25.0 wt. %) and talc (10.0 wt. %). The antiperspirant cream disclosed in Example VIII contains Cab-O-Sil HS-5.sup.1 (4.0 wt. %)

and Microthene FN510.sup.2 (6.0 wt. %). The waterproof mascara disclosed in Example IX contains Bentone 38 CG or Type (5.89 wt. %) and magnesium carbonate 309 (5.0 wt. %). The mascara disclosed in Example X contains Bentone 38 CG or Type (5.89 wt. %), talc 2755 (4.79 wt. % and Kolin 2747 (2.0 wt. %). The mascara disclosed in Example XII contains Bentone 38 CG or Type (5.89 wt. %), magnesium carbonate 309 (5.0 wt. %), Kaolin 2747 (2.0 wt. %) and polyethylene AC-617-A (1.0 wt. %). The lipstick disclosed in Example XII contains polyethylene 500 (6.84 wt. %). The composition disclosed in Example XIII contains talc (3.38 wt. %), pigment (10.51 wt. %) and sodium chloride (2.0 wt. %). The lipstick disclosed in Example XIV contains Bentone 38.sup.1 (1.0 w/w %) and mica cf.sup.3 (7.0 w/w %). The lipstick disclosed in Example XV contains micronized TiO.sub.2 in castor oil (8.0 w/w %) and mica SVA.sup.1 (10.0 w/w %). The lipstick disclosed in Example XVI contains micronized Tio2 in castor oil (8.0 w/w %), mica SVA.sup.1 (10.0 w/w %) and pigment (25.60 w/w %). The cosmetic emulsion disclosed in Example XVII contains solids in both admixture A and in the final emulsion.

One of skill in the art, reading Vatter, would understand that the solid consistency and the lack of flowability of the compositions disclosed therein are critical properties of the compositions. In order for a lipstick or antiperspirant to be useful, it must stay on the application site. If the disclosed compositions liquefied upon application of shear force, they would quickly disappear and constant reapplication would be required. Therefore, Vatter actually teaches away from compositions that liquefy upon application of shear force and would not render such compositions obvious.

Rejection over U. S. Patent 6,224,888 to Vatter further in view of U. S. Patent 4,992,478 to Geria

Applicants respectfully traverse the rejection of claim 51. A *prima facie* case of obviousness requires that (1) the prior art suggest to one of ordinary skill in the art that they

should make the claimed composition. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

In this case, the cited prior art does not provide the suggestion or a reasonable expectation of success. Even if, the compositions of Vatter were modified with the medicaments of Geria, the result would not be the applicant's claimed invention. Rather, the result would be a composition that lacked the property of being semi-solid at rest and liquefying upon application of shear force. Furthermore, the disclosure of Geria does nothing to remedy the failure of Vatter and cannot therefore, either alone or in combination, render the claimed invention obvious.

Conclusion

All currently pending claims are believed to be in conditions of allowance in light of the foregoing amendments and remarks, and an early notice thereof is respectfully solicited.

Respectfully submitted,

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EXHIBIT A

Amendments with Brackets and Underlining Showing Changes Made

1. A[n] solid-free oleaginous pharmaceutical or cosmetic carrier, comprising, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent, wherein said solidifying agent is selected from the group consisting of at least one long chain fatty alcohol having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbon atoms in its carbon backbone and further wherein said solidifying agent includes a substance selected such that under ambient conditions, the carrier is semi-solid at rest and liquefies upon its application of shear forces thereto.

26. A[n] solid-free oleaginous pharmaceutical or cosmetic composition comprising, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent, wherein at least one of said solidifying agent and said hydrophobic solvent has a therapeutic or cosmetic beneficial effect, wherein said solidifying agent is selected from the group consisting of at least one long chain fatty acid, having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbons in its carbon backbone and further wherein said solidifying agent includes a substance selected such that under ambient conditions, the carrier is semi-solid at rest and liquefies upon application of shear forces thereto.

EXHIBIT A

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37. A pharmaceutical or cosmetic composition comprising:

(a) a[n] solid-free oleaginous pharmaceutical or cosmetic carrier containing, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent; and

(b) a therapeutically or cosmetically effective amount of a biologically active substance;

wherein said solidifying agent is selected from the group consisting of at least one long chain fatty acid, having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbons in its carbon backbone and further wherein said solidifying agent includes a substance selected such that under ambient conditions, the carrier is semi-solid at rest and liquefies upon application of shear forces thereto.

EXHIBIT B

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1. A solid-free oleaginous pharmaceutical or cosmetic carrier, comprising, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent, wherein said solidifying agent is selected from the group consisting of at least one long chain fatty alcohol having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbon atoms in its carbon backbone and further wherein said solidifying agent includes a substance selected such that under ambient conditions, the carrier is semi-solid at rest and liquefies upon its application of shear forces thereto.

4. The pharmaceutical or cosmetic carrier of claim 1, wherein said hydrophobic solvent is selected from the group consisting of at least one marine animal derived oil, at least one terrestrial animal derived oil, at least one mineral oil, at least one silicone oil and at least one plant-derived oil.

5. The pharmaceutical or cosmetic carrier of claim 1, wherein said hydrophobic solvent includes an oil selected from the group consisting of olive oil, soybean oil, canola oil, rapeseed oil, cottonseed oil, coconut oil, palm oil, sesame oil, sunflower oil, safflower oil, rice bran oil, borage seed oil, syzigium aromaticum oil, hempseed oil, herring oil, cod-liver oil, salmon oil, corn oil, flaxseed oil, wheat germ oil, rape seed oil, evening primrose oil, rosehip oil, tea tree oil, melaleuca oil and jojova oil.

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7. The pharmaceutical or cosmetic carrier of claim 1, wherein said solidifying agent has at least one alkyl group side chain in its carbon backbone.

8. The pharmaceutical or cosmetic carrier or composition of claim 1, wherein said carbon backbone of said fatty acid or said fatty alcohol has at least one hydroxyl group at position α and β.

9. The pharmaceutical or cosmetic carrier of claim 1, wherein said carbon backbone of said fatty alcohol has at least one hydroxyl group at position α and β.

10. The pharmaceutical or cosmetic carrier of claim 1, wherein said carbon backbone of said fatty acid or said fatty alcohol has at least one hydroxyl group at positions 8-14.

11. The pharmaceutical or cosmetic carrier of claim 1, wherein said solidifying agent includes a 12-hydroxy fatty acid.

12. The pharmaceutical or cosmetic carrier of claim 1, wherein at least one of said solidifying agent and said hydrophobic solvent has a therapeutic or cosmetic beneficial effect.

26. A solid-free oleaginous pharmaceutical or cosmetic composition comprising, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent, wherein at least one of said solidifying agent and said hydrophobic solvent has a therapeutic or cosmetic beneficial effect, wherein said solidifying agent is selected from the group consisting of at least

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one long chain fatty acid, having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbons in its carbon backbone and further wherein said solidifying agent includes a substance selected such that under ambient conditions, the carrier is semi-solid at rest and liquefies upon application of shear forces thereto.

29. The pharmaceutical or cosmetic composition of claim 26, wherein said hydrophobic solvent is selected from the group consisting of at least one marine animal derived oil, at least one terrestrial animal derived oil, at least one mineral oil, at least one silicone oil and at least one plant-derived oil.

30. The pharmaceutical or cosmetic composition of claim 26, wherein said hydrophobic solvent includes an oil selected from the group consisting of olive oil, soybean oil, canola oil, rapeseed oil, cottonseed oil, coconut oil, palm oil, sesame oil, sunflower oil, safflower oil, rice bran oil, borage seed oil, syzigium aromaticum oil, hempseed oil, herring oil, cod-liver oil, salmon oil, corn oil, flaxseed oil, wheat germ oil, rape seed oil, evening primrose oil, rosehip oil, tea tree oil, melaleuca oil and jojova oil.

32. The pharmaceutical or cosmetic composition of claim 26, wherein said carbon backbone of said fatty acid or said fatty alcohol has at least one hydroxyl group at position α and β.

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33. The pharmaceutical or cosmetic composition of claim 26, wherein said carbon backbone of said fatty alcohol has at least one hydroxyl group at position α and β.

34. The pharmaceutical or cosmetic composition of claim 26, wherein said carbon backbone of said fatty acid or said fatty alcohol has at least one hydroxyl group at positions 8-14.

35. The pharmaceutical or cosmetic composition of claim 26, wherein said solidifying agent includes a 12-hydroxy fatty acid.

36. The pharmaceutical or cosmetic composition of claim 26, wherein said carbon backbone of said fatty alcohol has at least one hydroxyl group at position α and β.

37. A pharmaceutical or cosmetic composition comprising:

(a) a solid-free oleaginous pharmaceutical or cosmetic carrier containing, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent; and

(b) a therapeutically or cosmetically effective amount of a biologically active substance;

wherein said solidifying agent is selected from the group consisting of at least one long chain fatty acid, having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbons in its carbon backbone and further wherein said solidifying agent includes a substance selected such that under ambient conditions, the carrier is semi-solid at rest and liquefies upon application of shear forces thereto.

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40. The pharmaceutical or cosmetic composition of claim 37, wherein said hydrophobic solvent is selected from the group consisting of at least one marine animal derived oil, at least one terrestrial animal derived oil, at least one mineral oil, at least one silicone oil and at least one plant-derived oil.

41. The pharmaceutical or cosmetic composition of claim 37, wherein said hydrophobic solvent includes an oil selected from the group consisting of olive oil, soybean oil, canola oil, rapeseed oil, cottonseed oil, coconut oil, palm oil, sesame oil, sunflower oil, safflower oil, rice bran oil, borage seed oil, syzigium aromaticum oil, hempseed oil, herring oil, cod-liver oil, salmon oil, corn oil, flaxseed oil, wheat germ oil, rape seed oil, evening primrose oil, rosehip oil, tea tree oil, melaleuca oil and jojova oil.

43. The pharmaceutical or cosmetic composition of claim 37, wherein said solidifying agent has at least one alkyl group side chain in its carbon backbone.

44. The pharmaceutical or cosmetic composition of claim 37, wherein said carbon backbone of said fatty acid or said fatty alcohol has at least one hydroxyl group at position α and β.

45. The pharmaceutical or cosmetic composition of claim 37, wherein said carbon backbone of said fatty alcohol has at least one hydroxyl group at position α and β.

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46. The pharmaceutical or cosmetic composition claim 37, wherein said carbon backbone of said fatty acid or said fatty alcohol has at least one hydroxyl group at positions 8-14.

47. The pharmaceutical or cosmetic composition of claim 37, wherein said solidifying agent includes a 12-hydroxy fatty acid.

48. The pharmaceutical or cosmetic composition of claim 37, wherein at least one of said solidifying agent and said hydrophobic solvent has a therapeutic or cosmetic beneficial effect.

49. The pharmaceutical or cosmetic composition of claim 37, wherein said biologically active substance is selected from the group of consisting of an antibiotic agent, a free radical generating agent, an antifungal agent, an antiviral agent, a non-nucleoside reverse transcriptase inhibitor, a nucleoside-analog reverse transcriptase inhibitor, a protease inhibitor, a non-steroidal anti-inflammatory drug, an immunosuppressant, an antihistamine agent, an anti-inflammatory agent, a retinoid agent, a tar agent, an antipruritics agent and a scabicide agent.

50. The pharmaceutical or cosmetic composition of claim 49, wherein:

(a) said antibiotic agent is selected from the group consisting of chloramphenicol, tetracyclines, synthetic and semi-synthesic penicillins, beta-lactames, quinolones, fluoroquinolnes, macrolide antibiotics, peptide antibiotics, cyclosporines, erytromycin and clinndamycin;

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(b) said free radical generating agent is benzoyl peroxide;

(c) said antifungal agent is selected from the group consisting of azoles, diazoles, triazoles, miconazole, fluconazole, ketoconazole, clotrimazol, itraconazole griseofulvin, ciclopirox, amorolfine, terbinafine, Amphotericin B and potassium iodide;

(d) said antiviral agent is selected from the group consisting of flucytosine (5FC), Vidarabine, acyclovir and Gancyclovir;

(e) said nucleoside-analog reverse transcriptase inhibitor is selected from the group consisting of Zidovudine, Stavudine and Lamivudine;

(f) said non-nucleoside reverse transcriptase inhibitor is selected from the group consisting of Nevirapine and Delavirdine;

(g) said protease inhibitor is selected from the group consisting of Saquinavir, Ritonavir, Indinavir, Nelfinavir, Ribavirin Amantadine, Rimantadine and Interferon;

(h) said immunosuppressant is selected from the group consisting of Clobetasol proprionate, Halobetasol proprionate, Betamethasone diproprionate, Betamethasone valerate, Fluocinolone acetonide, Halcinonide, Betamethasone valerate, Fluocinolone acetonide, Hydrocortisone valerate, Triamcinolone acetonide, Hydrocortisone and hexachlorobenzene;

(i) said anti-inflammatory agent is a vitamin B3 or a derivative thereof;

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(j) said retinoid agent is selected from the group consisting of isotretinoin, adapalene and tretinoin;

(k) said tar agent is selected from the group consisting of coal tar and cade oil;

(l) said antihistamine agent is doxepine hydrochloride;

(m) said antipruritic agent is crotampiton; and

(n) said scabicide agent is selected from the group consisting of benzyl benzoate, malathion and crotamiton.

51. The pharmaceutical or cosmetic composition of claim 37, wherein said biologically active substance is effective in the treatment of a disease or disorder selected from the group consisting of psoriasis, acne, seborrhea, seborrheic dermatitis, alopecia and excessive hair growth, ichthyosis, wounds, burns, cuts, ulcers, psoriasis, seborrheic dermatitis of the face and trunk, seborrheic blepharitis, contact dermatitis, stasis dermatitis and exfoliative dermatitis.